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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,895	11/30/2001	David Samuel Cohen	111465.127	4229

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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
SIEFKE, SAMUEL P	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/997,895	COHEN, DAVID SAMUEL	
	Examiner	Art Unit	
	Samuel P. Siefke	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11,12,14-27,30-35 and 61-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,12,14-27,30-35 and 61-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 11-12,14-27,30-35,58-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The preamble states an optical bio-disc, but nothing in the claims reads on being optical.

How does the substrate rotate? The applicant deleted important information regarding how the substrate is rotated. Examiner suggest including the deleted information about controlling the rotation of the disc to overcome this rejection.

It is indefinite to claim an assay zone without any detection means or limitations that give the assay zone merit.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 11-12,14-27,30-35,61-63 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kellogg et al. (USPN 6,063,589).

Kellogg discloses a method and apparatus for performing microanalytic analyses on a platform by rotation, thereby utilizing the centripetal forces resulting from rotation of the platform to motivate fluid movement though microchannels embedded in the microplatform.

Kellogg discloses an optical bio-disc that comprises:

- substrate (col. 8, lines 6-38) having encoded information being readable by a disc drive assembly to control rotation of the disc (col. 8, line 37-col. 9, line 20);
- antechamber (fig 8-9H; entry port 401, antechamber);
- separation chamber in fluid communication with the antechamber (403 see figure 9G, col. 18, lines 52-60);
- fluid output port (406) located between the first and second portions of the separation chamber at a position selected to permit outward transmission

therethrough of a liquid component which also permits fluid flow of the plasma fraction therethrough (col. 18, lines 5-24, col. 18, lines 52-60);

- metering capillary (406 and 408,col. 18, lines 5-24) the outlet port turns into a metering capillary because it only allows the plasma fraction to pass through (see Fig 9H where a metered amount of plasma fraction is passed, shown as larger diagonal lines); also seen in fig. 3A-3J ref. 202.
- excess fluid outlet (203) or waste outlet that leads to a waste chamber (205) for collecting excess fluid from the metering capillaries(202) (fig. 3A-J, col. 10, lines 37-65).
- assay zone in fluid communication with the metering chamber so that when a sample is deposited in the antechamber and a rotation is applied, a metered amount of a liquid component is moved to the assay zone (col., lines 5-21).
- waste chamber (404) that is in fluid communication with both the metering chamber (fig. 8-9H).

The assay chamber includes optical detection of the reaction that occurs in the assay (col. 14, lines 6-35; col. 17, lines 5-21). With regards to claim 14, a disk drive is not claimed, and is not attributed patentable weight, even though Kellogg teaches a read head (col. 14, lines 6-34; col. 9, lines 16-20). Throughout Kellogg there are multiple embodiment which cover all the limitations of claimed subject matter in the instant application. With respect to claims 16-27 and 30-35, it is noted that Applicant recites limitation on the manner in which the biodisk is used. Such limitations are not attributed patentable weight in claims to the device. It is also noted that Kellogg

teaches a process in which incorporates the steps recited in these claims. Kellogg discloses that samples to be used in this apparatus comprise blood, plasma, serum, lymph, saliva, tears, cerebrospinal fluid, urine, sweat, plant and vegetable extracts, semen and as cites fluid and does not limit just to these specific examples (col. 6, lines 1-6). Kellogg also discloses a process of using an optical biodisc for separating, metering and analyzing a biological sample (col. 12, line 1 –col. 14, line 38). Kellogg discloses that the platform shown in Fig. 9a through 9H is for separating plasma from whole blood. Then analysis of the components in the sample are analyzed (col. 14, lines 6-34).

Kellogg discloses "disks of the invention are fabricated with an injection molded, optically clear base layer having optical pits in the manner of a conventional compact disk (CD). The optical pits provide means for encoding instrument control programming, user interface information, graphics and sound specific to the application and driver configuration." It is clear from this statement that the disc is encoded with control programming for controlling the rotation of the disc. It is also well known in the art that these types of bio-discs have rotation information encoded on the bio-disc itself that can be read by a reader similar to a CD reader.

Kellogg discloses a blood separation array seen in figures 9A-9H that separates blood and delivers a first component of the blood to collection area for assaying. Kellogg discloses an antibiotic assay disc as seen in figures 3A-3J where metering capillaries are used to meter a certain volume of sample fluid to be assayed. An overflow or excess outlet port 203 is connected to the metering capillaries to collect the

overflow (excess) of sample fluid that is not needed for analysis because a certain sample volume already occupies the metering capillaries. Kellogg discloses that the examples as seen in figures 3A-3J and 9A-9J are intended to further illustrate certain preferred embodiments of the invention and are not limiting in nature (col. 37. lines 22-25). Kellogg further discloses all the components can be employed in the microsystems platforms of the invention (col. 9, lines 21-23). Therefore one can construct the instant invention by employing all the components of Kellogg. The metering capillary with an attached over flow of fig. 3A ref. 202 and 203, would replace capillary 406 so that a metered amount of plasma fraction would be transferred to the assay collection 405 while the excess of the plasma fraction flows to wasted collection 405. One would require a metered amount of blood for quantification assays where a certain quantity of blood is needed to perform the assay.

Response to Arguments

Applicant's arguments with respect to claims 11-12,14-27,30-35,61-63 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel P. Siefke whose telephone number is 571-272-1262. The examiner can normally be reached on M-F 7:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1700. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sam P. Siefke

January 20, 2006

Jill Warden
Supervisory Patent Examiner
Technology Center 1700